UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE ROTAVIRUS VACCINES ANTITRUST LITIGATION	No. 2:18-cv-1734-JCJ (consolidated) JURY TRIAL DEMANDED

CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

TABLE OF CONTENTS

Page

1. Sugartown Pediatrics, LLC, and Schwartz Pediatrics S.C. (together, "plaintiffs"), individually and on behalf of a class of all others similarly situated, bring this action for treble damages under the antitrust laws of the United States against Merck Sharp & Dohme Corporation ("defendant" or "Merck"). Plaintiffs challenge Merck's anticompetitive scheme to enhance and maintain its monopoly power in the market for rotavirus vaccines sold in the United States ("Rotavirus Vaccine Market"). Plaintiffs purchased rotavirus vaccines directly from Merck and bring this action to recover overcharges that resulted from Merck's illegal monopolization scheme.

I. INTRODUCTION

2. This action challenges Merck's anticompetitive vaccine bundling scheme whereby Merck leverages its monopoly power in multiple pediatric vaccine markets to maintain its monopoly power in the Rotavirus Vaccine Market and, consequently, to charge supracompetitive prices to purchasers of its rotavirus vaccines.

3. Merck is one of the world's largest vaccines manufacturers and a leading manufacturer of vaccines in the United States. It is the sole United States manufacturer in the markets for multiple pediatric vaccines, including MMR (measles, mumps, and rubella), varicella, and human papilloma virus ("HPV"), holding 100% of United States sales for those vaccines. Merck is by far the dominant seller in the Rotavirus Vaccine Market, marketing its vaccine under the trade name RotaTeq; its only competitor in the Rotavirus Vaccine Market is GlaxoSmithKline plc ("GSK"), which markets its rotavirus vaccine under the trade name Rotarix.

4. Merck was the only seller of rotavirus vaccine in the United States from 2006 until 2008, when GSK received approval to market Rotarix. Even before the threat of competition from GSK, Merck had contracts that offered "bundled" price penalties that would condition non-penalty prices on buyer "loyalty" to an entire bundle of different Merck vaccines. In preparation for GSK's introduction of a competing rotavirus vaccine, Merck added a condition to its contracts that

required customers to buy all or nearly all of their pediatric rotavirus vaccines from Merck or face substantial price penalties on not only RotaTeq but also on all other bundled Merck vaccines (the "RotaTeq Bundled Loyalty Condition" or the "Merck Bundle"). This new bundle meant that any Merck customer who also wanted to buy significant amounts of Rotarix from GSK (a "Merck Disloyal Buyer" or "Disloyal Buyer")[1] would be faced with paying substantial penalties on any RotaTeq the customer continued to buy from Merck, *plus* substantial price penalties on all other Merck vaccines in the Merck Bundle (including those for which there is no other supplier).

5. Upon information and belief, the Merck Bundle forecloses competition in greater than 40% of the Rotavirus Vaccine Market. The Merck Bundle substantially forecloses competition by limiting GSK's ability to profitably win sales to foreclosed buyers with price cuts, thereby allowing Merck to maintain its monopoly share of the Rotavirus Vaccine Market despite continuing to charge foreclosed buyers monopoly prices. Because the Merck Bundle penalized Merck Disloyal Buyers with high penalty prices, GSK could maximize its profits by selling to such Disloyal Buyers at high prices just below the penalty prices charged by Merck.

6. In other words, the Merck Bundle bifurcated the market between Merck Loyal and Disloyal Buyers, reducing the ability of GSK to compete on price for the Loyal Buyers, and the incentive to compete on price for the Disloyal Buyers. As a result, the Merck Bundle incentivized GSK to maintain high prices instead of competing aggressively with Merck on the price of rotavirus vaccines. And as a result of the softened competition caused by the Merck Bundle, there was less competitive pressure on Merck to reduce pricing of RotaTeq.

7. Due to the Merck Bundle, instead of significantly decreasing the price of RotaTeq

[1] As opposed to Disloyal Buyers, "Merck Loyal Buyers" or "Loyal Buyers" are those that were willing to abide by the terms of Merck's Bundle.

when GSK entered the market, as would normally be expected to result from competitive entry into a monopoly market, Merck has maintained the price of RotaTeq at supracompetitive levels, actually *increasing* its list price despite facing competition from GSK.

8. As a result, plaintiffs and the proposed class paid artificially inflated prices for rotavirus vaccines.

II. PARTIES

A. Plaintiffs

9. Plaintiff Sugartown Pediatrics, LLC ("Sugartown") is a private pediatric medical practice with two office locations: one in Newtown Square, PA, and one in Malvern, PA, both of which are located in this District. During the class period (defined below), Sugartown purchased rotavirus vaccines (including RotaTeq directly from Merck) and was injured as a result of paying overcharges due to Merck's anticompetitive conduct as alleged herein.

10. Plaintiff Schwartz Pediatrics S.C. ("Schwartz") is a private pediatric medical practice with two office locations: one in Bartlett, IL and one in Schaumburg, IL. During the class period (defined below), Schwartz purchased rotavirus vaccines (including RotaTeq directly from Merck) and was injured as a result of paying overcharges due to Merck's anticompetitive conduct as alleged herein.

B. Defendant

11. Defendant Merck Sharp & Dohme Corporation ("Merck") is a company organized under the laws of New Jersey and headquartered in Whitehouse Station, New Jersey. Merck Sharp & Dohme Corporation is a wholly-owned subsidiary of the entity formerly known as Schering-Plough Corporation, which has in turn been renamed Merck & Co, Inc. Defendant Merck sells pediatric vaccines in the United States, including RotaTeq. Merck has facilities in numerous states, including research, development, and manufacturing facilities in this District. In particular, Merck

tests and manufactures vaccines at its "West Point" facility in Lansdale, PA, and has a major research facility located in North Wales, PA.

III. JURISDICTION AND VENUE

12. This action alleges violations of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and seeks relief under section 4 of the Clayton Act, 15 U.S.C. § 15(a), to recover treble damages, costs of suit, and reasonable attorneys' fees for the injuries sustained by plaintiffs and members of the class. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 4 and 15, and 28 U.S.C. §§ 1331 and 1337.

13. Venue is proper in this District under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b)(1)-(2) because Merck resides in and is an inhabitant of this District or is found or transacts business in this District and because a substantial part of the acts or omissions giving rise to the claims set forth herein occurred in this District.

14. This Court has personal jurisdiction over defendant because during the class period defendant had facilities involved in the research, development, and manufacturing of vaccines in this District; marketed and sold RotaTeq in this District; and has had substantial contacts within this District in furtherance of the anticompetitive activity alleged herein.

IV. INTERSTATE COMMERCE

15. The pharmaceutical vaccine products at issue in this case, including RotaTeq, are sold in interstate commerce, and Merck's conduct set forth herein substantially affected interstate commerce throughout the United States and caused antitrust injury throughout the United States.

V. BACKGROUND ON THE MANUFACTURE, REGULATION, AND SALE OF PEDIATRIC VACCINES IN THE UNITED STATES

A. How Vaccines Work

16. Vaccines help a patient develop immunity by, essentially, imitating an infection. A vaccine typically contains an agent that resembles a disease-causing micro-organism, and is often made from a weakened or killed form of the microbe, its toxins, or one of its surface proteins. The agent stimulates the body's immune system to recognize the agent as a threat, and in so doing, causes the body to create antibodies designed to fight the disease-causing organism. Thus, when exposed to a live version of the micro-organism in the future, the vaccinated body's immune system can more easily recognize and destroy these micro-organisms that it later encounters.

17. Because vaccines are meant to stimulate a particular immune response to a particular pathogen, vaccines for one disease (*e.g.*, rotavirus) are not interchangeable with vaccines for another (*e.g.*, polio).

18. Vaccines are manufactured in several different ways. These include live, attenuated vaccines, which contain a version of the living virus that has been weakened so that it does not cause disease, as well as inactivated vaccines, which are made by killing the virus during the process of making the vaccine.

19. For most vaccines—in particular, inactivated vaccines—the first dose does not provide as much immunity as possible. As a result, many vaccines require multiple doses to reach maximum immunity. In addition, because immunity can decrease over time, booster doses are often used to rebuild immunity. Booster doses are typically distinct from the initial vaccine given to a patient and can be configured in different ways.

20. Because of the large number of different diseases requiring vaccination, a child often needs multiple vaccine injections during a single visit to the doctor's office. As a result,

manufacturers have developed several combination vaccines, which inoculate against multiple diseases with a single dose injection.

B. FDA Approval of Vaccines and CDC Immunization Schedules

21. Vaccines are part of a category of pharmaceutical products known as biologics, or biopharmaceuticals. Biologics are drugs manufactured from biological sources as opposed to drugs that are produced through chemical synthesis. In the United States, both biologics and non-biologic pharmaceuticals are regulated by the Food and Drug Administration ("FDA"). However, biologics and non-biologic pharmaceuticals differ in that biologic products cannot receive FDA approval through the Abbreviated New Drug Application ("ANDA") process, which allows drugs that are demonstrated to be "bioequivalent" to an approved drug to be marketed as generics. Instead, in 2009, Congress passed the Biologics Price Competition and Innovation Act ("BPCIA") which provided an abbreviated approval pathway for licensure of biologic products that are "biosimilar" to an approved reference drug. However, even under this abbreviated approval pathway, in order to get FDA approval for a biologic product, a potential biologics manufacturer ("sponsor") must undertake expensive clinical trials to establish safety, purity, and effectiveness.

22. Vaccine licensure requires clinical trials and extensive lab testing that can take several years for completion. A sponsor who wishes to get approval for a new biologic product must first file an Investigational New Drug ("IND") application. The IND describes the vaccine, its method of manufacture, and quality control tests for release. After receiving approval for the IND, the sponsor may begin pre-licensure clinical trials in human subjects. There are three phases of clinical trials, each of which expands the number of human subjects. If at any stage in the process the data raise significant concerns about safety or effectiveness, the FDA may request additional information or halt ongoing clinical studies. If all three phases of clinical trials are successful, the sponsor may submit a Biologics License Application ("BLA"), which is a request for permission

to introduce a biologic product into interstate commerce. The FDA reviews the BLA and provides a final response letter to the sponsor, often requiring further clinical trials prior to final approval and licensure.

23. Each year, the Center for Disease Control's ("CDC") Advisory Committee on Immunization Practices ("ACIP") publishes immunization schedules recommended for pediatric and adolescent persons living in the United States. The schedules have been approved by the American Academy of Pediatrics, the American Academy of Family Physicians, and the American College of Obstetricians and Gynecologists.

24. The current version of the schedule requires the following 15 vaccinations, which protect against 16 diseases, for all people under 18 years of age: (1) hepatitis B; (2) rotavirus; (3) diphtheria, tetanus, and acellular pertussis ("DTaP"); (4) tetanus, diphtheria, and acellular pertussis booster ("Tdap"); (5) *haemophilus influenzae* type b ("Hib"); (6) pneumococcal conjugate; (7) inactivated poliovirus ("IPV"); (8) influenza; (9) measles, mumps, and rubella ("MMR"); (10) varicella virus; (11) hepatitis A; (12) meningococcal disease; (13) human papillomavirus ("HPV"); (14) meningococcal B; and (15) pneumococcal polysaccharide.

C. The Sale of Vaccines in the United States

25. In the United States, pediatric vaccines are sold separately to the public sector and the private sector. In the public sector, federal government agencies such as the Veterans Administration and the Department of Defense purchase vaccines under the Federal Supply Schedule ("FSS"). In addition, the CDC purchases vaccines based on prices negotiated by the Department of Health and Human Services under the Vaccines for Children ("VFC") program. The VFC program distributes these vaccines at no charge to state health departments and certain public health agencies for distribution to physicians' offices and public health clinics registered as VFC providers where they are used to vaccinate eligible children based on inability to pay. The

pricing obtained under the FSS and the VFC program is available only to specified government entities and is not offered to the private sector.

26. In the private sector, physician practices and hospitals purchase vaccines directly from manufacturers such as Merck or from wholesalers. Most physicians, physician practices, and hospitals purchase their vaccines pursuant to contracts negotiated by Physician Buying Groups ("PBGs") or other similar group purchasing organizations ("GPOs"). Those entities, and their roles in the marketplace, are explained further below.

VI. BACKGROUND ON ROTAVIRUS VACCINES

27. Rotavirus is the leading cause of severe acute gastroenteritis (vomiting and severe diarrhea) among infants and young children worldwide. The disease can be severe, leading to dehydration and death. Before rotavirus vaccines were prevalent, rotavirus disease was a common and serious health problem for children in the United States, with nearly all children in the United States experiencing at least one rotavirus infection before their fifth birthday. Every year before the vaccine was available, more than 200,000 children in the United States had to go to the emergency room, 55,000 to 70,000 had to be hospitalized, and up to 60 died.

28. The first vaccine for rotavirus, RotaShield, was licensed by Wyeth Pharmaceuticals and recommended by the CDC for routine childhood immunization in 1998. Wyeth Pharmaceuticals, however, withdrew the vaccine in 1999 due to safety concerns. Scientists associated the vaccine with a rare intestinal problem called intussusception, a potentially fatal telescoping of part of the bowel.

29. Merck was developing its RotaTeq vaccine while RotaShield was on the market. RotaTeq is a pentavalent vaccine; meaning that it protects patients against five rotavirus strains: G1, G2, G3, G4, and P1. It is created by combining human rotavirus genes with WC3 cow virus. It is administered in three oral doses that are provided as a ready-to-use liquid. The vaccine was

created by Dr. H. Fred Clark of the Wistar Institute of the University of Pennsylvania and Dr. Paul Offit, Chief of Infectious Diseases at the Children's Hospital of Philadelphia ("CHOP"). From 1992 to 1993, Merck licensed the RotaTeq vaccine from CHOP and initiated an efficacy trial, with Drs. Clark and Offit as primary investigators. This trial led to a blinded, randomized, placebo-controlled proof-of-concept trial in 439 infants aged 2–6 months old, conducted between 1993 and 1994.

30. After Wyeth withdrew its RotaShield vaccine in 1999, Merck accelerated its testing. In March 2001, Merck began a double-blind, randomized, placebo-controlled "Rotavirus Efficacy and Safety Trial" ("REST trial"), which was believed to be large enough to demonstrate the efficacy of RotaTeq conclusively and to rule out increased intussusception risk. The REST trial tested RotaTeq on 68,000 infants administered at 2–3 months followed by two subsequent doses, each 1–2 months after the last. With the successful results, RotaTeq was licensed by the FDA in February 2006. At the time, Merck was the only manufacturer selling a rotavirus vaccine in the United States. Like many of Merck's vaccines, RotaTeq is routinely administered to infants and young children as part of a regular vaccine schedule recommended by the CDC.

31. GSK's Rotarix was developed by Dr. Richard Ward and Dr. David Bernstein at Cincinnati Children's Hospital Medical Center in the early 1990s. Rotarix is an oral live attenuated human vaccine administered in two doses and is provided as a powder that is reconstituted before administration. Unlike RotaShield or Merck's RotaTeq, Rotarix is a single strain or monovalent vaccine, which means it specifically protects against one strain of rotavirus, the G1 strain, which is the strain responsible for the majority of infections in the United States, and induces some cross-protection against other less-common strains (G3, G4, and G9). Rotarix is also unique among other rotavirus vaccine candidates in being a human rather than a rhesus or bovine reassortant virus.

32. In 1995, Cincinnati Children's Hospital entered a licensing agreement with the Virus Research Institute, which merged with T Cell Sciences in August 1998 to form Avant Immunotherapeutics. Avant funded a Phase II clinical trial of Rotarix from August 1997 to June 1998 with Dr. Bernstein, now a consultant to Avant and Cincinnati Children's Hospital researcher, as the trial's principal investigator. This trial proved successful and there were few adverse events in the children tested. Avant completed a 2-year extension in May 2000 which showed that effectiveness remained after two years from inoculation. GSK (then, SmithKline Beecham) negotiated worldwide marketing rights in 1997. GSK completed I/II bridging and Phase II trials in 2002. It then initiated a Phase III trial of 63,000 children aged 6 weeks to 6 months in the third quarter of 2003. The Phase III trial was billed by GlaxoSmithKline Biologicals as the largest infant vaccine trial ever conducted. Rotarix was approved by the FDA in April 2008 for sale in the United States.

33. Revised ACIP recommendations for the use of rotavirus vaccine were published in February 2009. Because of similar estimates of efficacy and safety, neither ACIP nor the Academies of Pediatrics or Family Physicians state a preference for one vaccine over the other. In addition, ACIP recommends that the rotavirus vaccine series be completed with the same product whenever possible. In other words, if a patient begins the series with RotaTeq, it should complete that series with RotaTeq and should not switch to Rotarix, and vice versa.

34. Merck and GSK are the only companies that market a rotavirus vaccine in the United States. But despite competition from Rotarix—a product that the CDC has stated is just as effective as RotaTeq in preventing rotavirus infection—Merck continues to dominate the Rotavirus Vaccine Market in the United States, currently enjoying over 70% market share.

VII. THE VACCINES INDUSTRY AND ITS RELEVANT MARKETS

A. Vaccine Manufacturers

35. The sales of vaccines are large and rapidly expanding. In 2005, global vaccine sales generated approximately $10 billion in revenue, and that number more than quadrupled to approximately $41 billion in 2015. Vaccines are commonly segmented into two target segments: adult and pediatric.

36. In recent decades, vaccine markets in the United States have become highly concentrated. In 1967, 26 different companies held vaccine licenses in the United States, but by 2002, that number had dropped to 12. In 2008, only four companies sold pediatric vaccines in the United States: Merck, GSK, Sanofi Pasteur Inc. ("Sanofi"), and Pfizer, Inc. ("Pfizer"). Novartis began selling one pediatric vaccine in the United States in February 2010 but sold its pediatric vaccine business to GSK in March of 2015. After Novartis sold its vaccine business to GSK, there were again only four manufacturers in the United States selling the pediatric vaccines recommended on the ACIP schedule. The pediatric vaccine marketplace is highly concentrated among Merck, Sanofi, GSK, and Pfizer.

37. In addition to this concentration, two of the largest vaccines manufacturers, Merck and Sanofi, have reached agreements to cooperate in various ways in their sales of vaccines. Since 1994, Merck and Sanofi have operated a joint venture, Sanofi Pasteur MSD, which markets both companies' lines of vaccines in Europe. In the United States, because Merck and Sanofi have complementary vaccine lines and similar bundling programs, most PBGs provide access to, monitor, and enforce loyalty to both companies' complementary bundles.

38. The following chart indicates the vaccine products manufactured by Merck and its rivals in 2011:

	Merck	Sanofi	GSK	Novartis	Pfizer
Hepatitis B	Recombivax Comvax*[3]		Engerix B Twinrix*[2] Pediarix*		
DTaP		Daptacel Pentacel*	Infanrix Kinrix* Pediarix*		
Tdap		Adacel	Boostrix		
Polio (IPV)		IPOL Pentacel*	Kinrix* Pediarix		
Pneumococcal	Pneumovax				Prevnar
Hib	PedvaxHIB[3] Comvax*	ActHIB Pentacel*	Hiberix		
Rotavirus	RotaTeq		Rotarix		
MMR	MMRII				
Varicella	Varivax ProQuad* Zostavax				
Hepatitis A	Vaqta		Havrix Twinrix*		
Meningitis (MCV4)		Menactra Menomune		Menveo	
HPV	Gardasil		Cervarix		

[2] A "*" indicates a combination vaccine. Additionally, Twinrix can only be used for adults and therefore is not functionally interchangeable with pediatric Hepatitis A vaccines.

[3] Along with Comvax, PedvaxHIB was the subject of a recall in late 2007. Merck had limited supplies for sale from 2007 through 2010.

B. Relevant Product Markets

39. The Merck Bundle effectively leveraged Merck's market power in a number of pediatric vaccine markets to maintain its monopoly power in the Rotavirus Vaccine Market. To the extent that plaintiffs must prove monopoly power circumstantially by first defining a relevant product market, the following eight product markets are potentially relevant to plaintiffs' antitrust claims.

1. Rotavirus Vaccine Market

40. The sale of rotavirus vaccines in the United States is a relevant product market.

41. The Rotavirus Vaccine Market contains all FDA-approved vaccines that inoculate against rotavirus.

42. In February 2006, the FDA licensed RotaTeq, a rotavirus vaccine marketed by Merck, for sale in the United States. RotaTeq is administered in a three-dose series, with doses administered at ages two, four, and six months.

43. In April 2008, the FDA licensed Rotarix, a rotavirus vaccine marketed by GSK, for sale in the United States. Rotarix is administered in a two-dose series, with doses administered at ages two and four months. Since April 2008, Rotarix has been the only rival to RotaTeq in the Rotavirus Vaccine Market.

44. Revised ACIP recommendations for the use of rotavirus vaccine were published in February 2009. Because of similar estimates of efficacy and safety, neither ACIP nor the Academies of Pediatrics or Family Physicians state a preference for either Rotarix or RotaTeq.

45. The ACIP pediatric immunization schedule recommends rotavirus vaccine as a two- or three-dose series, with the first dose at two months, the second at four months, and the third at six months (if RotaTeq is used).

46. There are no reasonably available substitutes for rotavirus vaccines.

47. Prior to 2008, Merck had 100% market share in the Rotavirus Vaccine Market. After GSK entered the market in 2008, Merck's market share dropped, but on information and belief remained above 68% through the present day. In 2016, Merck's market share was 73%.

48. At all relevant times, Merck possessed monopoly power in the Rotavirus Vaccine Market.

49. A small but significant, non-transitory increase above competitive prices for rotavirus vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

50. Due to the conduct challenged herein, Merck has sold its rotavirus vaccine at supracompetitive prices well in excess of marginal costs and in excess of the competitive price, and has enjoyed high profit margins.

2. Measles, Mumps, and Rubella ("MMR") Vaccine Market

51. The sale of MMR vaccines in the United States is a relevant product market.

52. The MMR Vaccine Market contains all FDA-approved vaccines that inoculate against the measles (rubeola), mumps, and rubella (German measles) viruses.

53. The ACIP pediatric vaccine schedule recommends that children get a two-dose series of MMR vaccine at ages twelve through fifteen months and at ages four through six years.

54. There are two MMR vaccines available in the United States, MMRII and ProQuad. ProQuad is a combination vaccine that also inoculates against Varicella. Merck sells both MMRII and ProQuad.

55. There are no reasonably available substitutes for MMR vaccines.

56. A small but significant, non-transitory increase above competitive prices for MMR vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

57. Merck is the sole provider of MMR vaccines in the United States and has been the

sole provider for the relevant period.

3. Pediatric Varicella Vaccine Market

58. The sale of pediatric varicella vaccines in the United States is a relevant product market.

59. The Pediatric Varicella Vaccine Market contains all vaccines that inoculate against the varicella virus, commonly known as chicken pox, that are FDA-approved for use in children from birth to 18 years of age.

60. The ACIP pediatric vaccine schedule recommends that children get a two-dose series of varicella vaccine at ages twelve through fifteen months and at ages four through six years.

61. There are two pediatric varicella vaccines available in the United States: Varivax and ProQuad. ProQuad is a combination vaccine that also inoculates against MMR. Merck sells both Varivax and ProQuad.

62. Merck and GSK also sell adult varicella vaccines, brand name Zostavax and Shingrix, to prevent and treat Shingles, a disease which results from a recurrence of the varicella virus in adults. Merck received a license to sell Zostavax in 2006 for use in people 60 years of age and older and GSK received a license to sell Shingrix in 2017 for use in people 50 years of age and older. Neither is indicated for pediatric use and neither is substitutable for pediatric varicella vaccines.

63. There are no reasonably available substitutes for pediatric varicella vaccines.

64. A small but significant, non-transitory increase above competitive prices for pediatric varicella vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

65. Merck is the sole provider of pediatric varicella vaccines in the United States and has been the sole provider for the relevant period.

4. HPV Vaccine Market

66. The sale of HPV vaccines in the United States is a relevant product market.

67. The HPV vaccine inoculates against human papillomavirus infection.

68. The HPV Vaccine Market contains all FDA-approved vaccines that inoculate against human papillomavirus, which can cause a variety of cancers, such as cervical cancer in women, and genital warts in both men and women.

69. The ACIP pediatric vaccine schedule recommends that adolescents receive a three-dose series of HPV vaccine on a schedule of 0, 1 to 2, and 6 months, to all adolescents aged 11 through 12 years.

70. During the relevant period, there have been two HPV vaccines available in the United States: Gardasil and Cervarix. Merck sells Gardasil, which was licensed in June 2006, and is one of its most profitable products, grossing over $1.9 billion in 2015. GSK sells Cervarix, which was licensed by the FDA in 2009.

71. There are no reasonably available substitutes for HPV vaccines.

72. A small but significant, non-transitory increase to competitive prices for HPV vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

73. Merck was the sole provider of HPV vaccines in the United States until 2009, and has maintained a dominant share of the HPV Vaccine Market since then and throughout the relevant period. In 2015, Merck had a 99.7% share in the HPV Vaccine Market, and in 2016, GSK exited the market, restoring Merck's 100% market share.

5. Hepatitis A Pediatric Vaccine Market

74. The sale of pediatric hepatitis A vaccines in the United States is a relevant product market.

75. The hepatitis A vaccine inoculates against the hepatitis A virus, which causes liver

disease.

76. The Hepatitis A Pediatric Vaccine Market contains all FDA-approved vaccines for use in children from birth to 18 years of age that inoculate against the hepatitis A virus.

77. The ACIP pediatric vaccine schedule recommends that children get a two-dose series of hepatitis A vaccine at ages twelve through twenty-three months and a second dose six to eighteen months after the first dose.

78. There are two pediatric hepatitis A vaccines available in the United States, Havrix and Vaqta. GSK sells Havrix and Merck sells Vaqta. GSK also sells Twinrix, a combination hepatitis A and hepatitis B vaccine, but it can only be used for adults and therefore is not functionally interchangeable with pediatric hepatitis A vaccines.

79. There are no reasonably available substitutes for pediatric hepatitis A vaccines.

80. A small but significant, non-transitory increase above competitive prices for hepatitis A pediatric vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

6. Hepatitis B Pediatric Vaccine Market

81. The sale of pediatric hepatitis B vaccines in the United States is a relevant product market.

82. Hepatitis B vaccines inoculate against the hepatitis B virus, which can cause lifelong infection, cirrhosis (scarring) of the liver, liver cancer, and liver failure.

83. The Hepatitis B Pediatric Vaccine Market contains all FDA-approved vaccines that inoculate against the hepatitis B virus and are approved for use in children aged 0 to 18.

84. The ACIP pediatric vaccine schedule recommends that children get three doses of hepatitis B vaccine: at birth, between one and two months, and between six and eighteen months.

85. There are currently four different hepatitis B vaccines available in the United States.

GSK sells Engerix B and Pediarix, a combination vaccine that includes pediatric hepatitis B vaccine. Merck sells Recombivax HB and sold Comvax until it was discontinued. GSK also sells Twinrix, a combination hepatitis A and hepatitis B vaccine, but it can only be used for adults and therefore is not functionally interchangeable with pediatric hepatitis B vaccines.

86. There are no reasonably available substitutes for pediatric hepatitis B vaccines.

87. A small but significant, non-transitory increase above competitive prices for pediatric hepatitis B vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

7. *Haemophilus Influenzae* Type B ("Hib") Vaccine Market

88. The sale of *haemophilus influenzae* type b ("Hib") vaccines in the United States is a relevant product market.

89. Hib vaccines inoculate against a type of bacteria called *haemophilus influenzae* type b, which can cause meningitis (an infection of the covering of the brain and spinal cord), pneumonia (lung infection), and epiglottitis (a severe throat infection).

90. The Hib Vaccine Market contains all FDA-approved vaccines that inoculate against *haemophilus influenzae* type b.

91. The ACIP pediatric vaccine schedule recommends that children get three or four doses of Hib vaccine at two, four, and six months (depending on the brand of vaccine used), and a booster dose between twelve and fifteen months.

92. There are currently five different Hib vaccines available in the United States. The five vaccines are ActHIB, Hiberix, PedvaxHIB, Pentacel, and Menhibrix. GSK sells Hiberix and Menhibrix, the latter of which is only approved by ACIP for the last dose of the Hib series. Merck sells PedvaxHIB. Sanofi sells ActHIB and Pentacel. Merck also sold Comvax until March 31, 2014, at which point it was discontinued.

93. There are no reasonably available substitutes for Hib vaccines.

94. A small but significant, non-transitory increase above competitive prices for Hib vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

95. Sanofi has held a dominant share of the Hib Vaccine Market throughout the relevant period. Merck suspended production of both of its Hib vaccines from 2007 through 2009 because inspections of its facilities revealed contamination by foreign bacteria. Between 2010 and 2013, Merck's market share in the Hib Vaccine Market (including Pedvax HIB and Comvax) increased steadily from about 8% to 18%. However, Merck and Sanofi co-marketed their largely complementary line of vaccines, and their combined share in the Hib Vaccine market was greater than 98%, leaving GSK with less than 2%.

8. Pneumococcal Vaccine Market

96. The sale of pneumococcal vaccines in the United States is a relevant product market.

97. Pneomococcal vaccines inoculate against the bacteria *Streptococcus pneumoniaea* which can cause pneumonia, meningitis, and sepsis.

98. The Pneumococcal Vaccine Market contains all FDA-approved vaccines that inoculate against *Streptococcus pneumoniaea*. There are two types of Pneumococcal vaccines sold in the United States, pneumococcal conjugate vaccine (PCV 7 and PCV13) and pneumococcal polysaccharide vaccine (PPSV23).

99. PCV7 and PCV13 vaccines are sold by Pfizer under the brand names Prevnar and Prevnar13. Prevnar13 was approved by the FDA for sale in the United States on February 24, 2010.

100. PPSV23 vaccines are sold by Merck under the brand name Pneumovax. Pneumovax was licensed for sale in the United States in 2011.

101. The ACIP pediatric vaccine schedule recommends doctors administer three doses of Prevnar to infants at two, four, and six months, and a fourth dose between twelve and fifteen months.

102. The CDC recommends a dose of Pneumovax for adults over the age of 65, even if they have gotten one or more doses of pneumococcal vaccine before the age of 65, and also recommends the use of Pneumovax as a catch-up vaccine for children ages 2-18 years who have not completed the recommended infant schedule.

103. There are no reasonably available substitutes for pneumococcal vaccines.

104. A small but significant, non-transitory increase above competitive prices for pneumococcal vaccines would not cause a significant loss of sales such as to make the increase unprofitable.

C. The Relevant Geographic Market is the United States

105. The relevant geographic market for the vaccine product markets described above is the United States. Vaccines are subject to a complex regulatory framework under which drug approval in the United States is governed by the FDA. In addition, prices vary widely as between inside and outside of the United States, respectively, due to different national regulatory regimes.

D. Barriers to Entry

106. United States vaccines markets, including pediatric vaccine markets, are characterized by high barriers to entry including substantial upfront fixed costs, intellectual property protection, and substantial regulatory hurdles. As one academic study notes, "threat of new entrants in this market is seemingly low as the barriers to entry when developing biological

products like vaccines are quite high."[4]

107. Vaccine manufacturing is characterized by high fixed costs and economies of scale. The processes used to manufacture vaccines often use proprietary cell lines and virus strains that are difficult to duplicate. In addition, a manufacturer cannot bring a vaccine to market in the United States without obtaining an FDA license through the regulatory process for biologics. The ANDA process is not available for biologics in the United States, and the approval process for biosimilar products requires new entrants to perform costly clinical studies in order to obtain FDA approval. Those time-consuming and costly clinical trials may or may not result in licensing for a new vaccine. As a result, fixed costs are high in United States vaccine markets and barriers to entry make it difficult for new companies to develop, license, and bring a new vaccine to market.

108. In addition to large upfront costs for R&D and capital expenditures necessary to manufacture a vaccine, there are substantial economies of scale in vaccine manufacturing. Thus, established firms with larger output can have lower per-unit costs than new entrants with lower volumes due to the ability to spread such costs as plant administration, quality control, laboratory operation, health and safety, and utilities over a higher volume of output.

109. Another barrier to entry is created by the long period of time required to gain FDA approval for a vaccine. Even if an entrant were willing to incur the costs of entry today, it would not be able to compete with incumbent manufacturers for several years until it received a license from the FDA to market its product in the United States. For example, as described above, GSK initiated Phase III trials for Rotarix in 2003, but was not licensed by the FDA to make sales in the

---

[4] Kevin W. Caves & Hal J. Singer, *Bundles in the Pharmaceutical Industry: A Case Study of Pediatric Vaccines* at 14 (2011) (quoting Frost & Sullivan, Global Vaccines Market, Dec. 7, 2009, at 4), *available at* https://www.law.berkeley.edu/wp-content/uploads/2015/04/Caves-Singer-Bundles-in-the-Pharmaceutical-Industry-2011.pdf.

United States until five years later in 2008. Altogether it can take more than 10 years to bring a new vaccine to market.

110. The existence of high entry barriers is also indicated by the rarity of market entry. For example, Merck has yet to experience any competition in the MMR vaccine market since the introduction of its MMR vaccines more than forty years ago. Likewise, in the Rotavirus Vaccine Market, high entry barriers are confirmed by the lack of additional entry over the last 10 years.

VIII. MERCK HAS WILLFULLY MAINTAINED ITS MONOPOLY POWER IN THE ROTAVIRUS VACCINE MARKET

A. Merck Has Monopoly Power in the Rotavirus Vaccine Market and Others

111. Merck has had monopoly power in the following markets throughout the relevant period and up to the present: the Rotavirus Vaccine Market, the MMR Vaccine Market, the Varicella Vaccine Market, and the HPV Vaccine Market. In addition, at certain times during the relevant period, Merck has had market power in the Hepatitis B Pediatric Vaccine Market and the Hepatitis A Pediatric Vaccine Market. Merck has had the power to foreclose competition and price above competitive levels in each of these markets during the relevant period.

112. From the time it received FDA approval to sell RotaTeq in February 2006 until GSK entered the market in 2008, Merck had a 100% monopoly in the Rotavirus Vaccine Market in the United States. Merck also had a 100% monopoly in the MMR, Varicella, and HPV Vaccine Markets, as well as a substantial share in the Hepatitis A and Hepatitis B Pediatric Vaccine Markets.

113. In 2008, GSK planned to bring a competing rotavirus vaccine, Rotarix, to market. Rotarix was approved by the FDA in April 2008 for sale in the United States. At the time, GSK sold competing hepatitis A, hepatitis B, and Hib pediatric vaccines, but did not sell an MMR vaccine, a Varicella vaccine, or an HPV vaccine (until Cervarix was introduced later).

114. Merck responded to this competition from GSK not by lowering the price of RotaTeq as economics would predict, but instead by using the Merck Bundle to foreclose competition from GSK. Upon information and belief, these contracts foreclose competition in more than 40% of the relevant market, and they have allowed Merck to leverage its monopoly power in multiple pediatric vaccine markets to maintain its monopoly power in the Rotavirus Vaccine Market. This scheme effectively divided the Rotavirus Vaccine Market in a way that softened competition by impairing competitive incentives, and thereby allowed both Merck and GSK to price at monopoly levels even after GSK entered the market with Rotarix.

B. Merck Implemented the Merck Bundle Through a Series of Exclusionary Contracts

115. Merck was the sole seller of pediatric rotavirus vaccine in the United States from 2006 until GSK received approval to sell Rotarix in 2008. In response to this competitive threat from GSK in the Rotavirus Vaccine Market, Merck added an exclusionary RotaTeq Bundled Loyalty Condition to its contracts, thereby bundling RotaTeq with its other pediatric vaccines.

116. Under the RotaTeq Bundled Loyalty Condition, Merck customers must agree to purchase all or nearly all of their rotavirus vaccines from Merck, and thus forego purchasing Rotarix from GSK. Customers who do not abide by this loyalty requirement would face paying steep disloyalty penalties not only on their purchases of RotaTeq, but also on all of their purchases of hepatitis A, hepatitis B, Hib, Varicella, MMR, and HPV vaccines from Merck. Thus, customers who would purchase Rotarix from GSK are penalized by being forced to pay substantially higher prices for all of the vaccines in the Merck Bundle—including those vaccines for which Merck is the sole seller—from 2% to 58% higher, depending on the vaccine.

117. As part of the scheme challenged in this case, in May 2008, and in anticipation of competition from GSK in the rotavirus vaccine market, Merck sent a letter to Atlantic Health Partners ("AHP"), a PBG, to amend Merck's contract with AHP so that it would now require 80%

market share loyalty on Merck's rotavirus vaccine in order to avoid bundled penalty prices on Merck's MMR II, Pneumovax23, ProQuad, Varivax, Gardasil, and Zostavax vaccines. This new condition is the RotaTeq Bundled Loyalty Condition.

118. Although physicians, practices, and hospitals purchase vaccines directly from manufacturers, most do so pursuant to contracts negotiated by PBGs or other similar GPOs (collectively referred to as "buying groups").

119. PBGs are typically privately held, for-profit entities, with membership consisting of thousands of family practices, pediatricians, and other independent medical practices. PBGs perform various services on behalf of their members, including coordinating and aggregating member purchases of vaccines and other healthcare supplies through group purchasing contracts with major vaccine manufacturers and medical supply distributors. Because PBGs seldom charge membership dues or participation fees, most or all of their compensation typically comes in the form of rebates and administrative fees paid by vendors (based on PBG members' aggregate expenditures). To qualify for non-penalty vaccine prices, PBGs typically require that participating practices agree to contractual terms that typically include manufacturer exclusivity. Manufacturers grant rebates to PBGs based on their success in enrolling practices and aggregating purchase volumes. The receipt of these administrative fees and rebates is usually dependent on the PBG's compliance with the loyalty terms contained in their contracts, and thus provides a strong incentive for the PBG to ensure its members maintain loyalty to the manufacturer. PBGs may share some portion of these rebates with their members, and may also keep some portion for themselves.

120. Through the bundling scheme alleged herein, Merck has coopted the PBGs—who are paid by the vaccine manufacturers even though they ostensibly work on behalf of physicians—to impose and enforce its anticompetitive and exclusionary conduct. Continuing to the present,

Merck has imposed the Merck Bundle through a series of exclusionary contracts with PBGs and other GPOs, and by extension, on the providers and institutions that are members of these groups. On information and belief, before GSK entered the Rotavirus Vaccine Market, Merck already had agreements in place with buying groups that provided buyers certain contract prices for all vaccines in Merck's portfolio if (and only if) the buyers committed to buying all or nearly all of their hepatitis A and hepatitis B vaccines from Merck. Notably, before GSK received approval for Rotarix, Merck's contract prices were not contingent upon loyalty to RotaTeq, a vaccine for which Merck faced no competition, unlike with the vaccines for hepatitis A, hepatitis B, and Hib. In response to GSK's entry into the Rotavirus Vaccine Market, however, Merck added the RotaTeq Bundled Loyalty Condition to its contracts. This condition required the purchaser either to maintain a high RotaTeq share (such as 90% or 100%) of its total rotavirus vaccine purchases, or to be penalized by losing contract prices on all of Merck's pediatric vaccines and being forced to pay the higher "list" prices for the Merck vaccines. Merck has continued to sign additional contracts and contract amendments through the present that include the RotaTeq Bundled Loyalty Condition.

121. After the addition of the RotaTeq Bundled Loyalty Condition, customers' receipt of bundled contract prices for Merck's portfolio of pediatric vaccines became contingent on maintaining loyalty to RotaTeq. Buying groups generate revenue primarily through the administrative fees and rebates paid by manufacturers as a percent of the buying group's total purchases of the manufacturer's products. When Merck added the RotaTeq Bundled Loyalty Condition to its contracts, however, it also made receipt of these rebates contingent upon the PBG or GPO maintaining member loyalty to RotaTeq, whereas before the RotaTeq Bundled Loyalty Condition was added, loyalty was only required on Merck's other vaccines. For example, under

the new RotaTeq Bundled Loyalty Condition, if a buying group's members failed to meet their collective loyalty requirement on RotaTeq, that buying group would now face a catastrophic event, namely losing its administrative fee earned on *all* of its members' pediatric vaccine purchases from Merck, not just those earned on RotaTeq purchases.

122. Because Merck and Sanofi manufacture vaccines in complementary rather than competing markets (the only exception being the Hib Vaccine Market, which Merck withdrew from for much of the relevant period), many of Merck's bundled loyalty contracts allow customers to purchase Sanofi's complementary vaccines, but *forbid* the customer from purchasing competing vaccines from GSK. Thus, buying groups who sign contracts with Merck to offer bundled pricing to their members generally cannot enter into a simultaneous agreement with GSK to offer GSK's products to their members at bundled prices. In addition, in order not to jeopardize their administrative fees and rebates, Sanofi/Merck buying groups must actively discourage their members from purchasing GSK's Rotarix by threatening to remove the member from the group, which would force the member to pay penalty prices for all of Merck's bundled vaccines.

123. The following summarizes some of the PBGs and GPOs that have exclusionary contracts with Merck that contain the RotaTeq Bundled Loyalty Condition, requiring *de facto* exclusivity or near exclusivity on Merck's rotavirus vaccines:

1. CNHN Vaccine Group

124. CNHN Vaccine Group offers a vaccine group purchase program with Merck. CNHN Vaccine Group's Purchase Information explains that:

> **To receive our CNHN contract pricing, members agree to purchase Sanofi or Merck products where competing vaccines exist.** In return our members receive the region's best pricing on the full portfolio of Sanofi and Merck vaccines. Occasionally, a competing product may briefly be lower-priced; however, CNHN practices realize significant savings when you calculate the total vaccine purchases made annually by our practices. . . . **CNHN members cannot selectively participate in CNHN vaccine contract for some vaccine and simultaneously**

> **purchase competing products off contract.** CNHN pricing is tiered to contract performance. The closer we come to 100% ordering compliance, the better we all do. CNHN does not endorse practices ordering small amounts of competing products. Doing so violates our contract terms and jeopardizes group pricing for all our participating CNHN members.[5]

125. This language indicates that, because of the incentives created by the Merck Bundle, CNHN does not offer GSK vaccines, and actively discourages its members from purchasing Rotarix or other GSK vaccines outside of its contract because that could lead to steep penalties from Merck under these contracts.

2. Atlantic Health Partners

126. Atlantic Health Partners is a leading PBG specializing in vaccines. AHP has negotiated exclusive vaccine purchasing contracts with both Merck and Sanofi. Participating physicians' practices agree to exclusivity on rotavirus vaccines (as well as others) in exchange for avoiding penalties on its prices for Merck's vaccine portfolio.

3. CCPA Purchasing Partners

127. CCPA Purchasing Partners offers a "Merck Contract Only" that requires physician practices to agree to "purchase Merck's Hepatitis A (Vaqta), Hepatitis B (Recombivax HB), MMR (M-M-R II), Varicella (Varivax), HPV (Gardasil/Gardasil9), Rotavirus (RotaTeq), HIB (Pe[d]Vax HIB) and Pneumococcal (Pneumovax23) vaccine products as needed. By selecting this option, [the] practice agrees **<u>not</u>** to purchase GlaxoSmithKline's Havrix, Engerix-B, Twinrix, Hiberix, Cervarix, Rotarix, and Pediarix products, and/or any other vaccine product that competes with the Merck products noted above. It is understood that failure to comply with these compliance terms

---

[5] *CNHN Vaccine Group Purchase Information*, *available at* https://childrensnational.org/-/media/cnhs-site/files/healthcare-providers/cnhn/vaccine contract.pdf?la=en&hash=9EE24D92C0B1D5A8CB84267B688E0B6205C8877.

may result in price increases, loss of administrative awards, and termination of [the] practice from CCPAPP's Merck contract."[6]

128. The CCPA Purchasing Partners Vaccine Contracting Guide further explains that "[i]f your practice is participating ***only*** in the Merck agreement (and not the Sanofi Pasteur agreement with CCPAPP), your practice must agree to purchase as needed: Merck's Hepatitis A (Vaqta), Hepatitis B (Recombivax HB), Measles, Mumps and Rubella Virus (M-M-R II), Varicella (Varivax), HPV (Gardasil/Gardasil9), Rotavirus (RotaTeq), HIB (PedvaxHib) and Pneumococcal (Pneumovax 23) vaccine products. By selecting this option, your practice agrees not to purchase GlaxoSmithKline's Hepatitis A (Havrix), Hepatitis B (Engerix-B), Hepatitis A-Hepatitis B combination (Twinrix), HPV (Cervarix), Rotavirus (Rotarix), HIB (Hiberix), and Polio-DTap-Hepatitis B combination (Pediarix) products, and/or any other vaccine product that competes with the Merck products noted above."[7]

4. CASA Physicians Alliance

129. CASA Physicians Alliance offered its members a Merck contract that included "Core Products," which "should be purchased through Merck or one of the Prime Distributors approved by Merck in lieu of equivalent vaccines from any other vendors."[8] The Core Products included RotaTeq. If CASA members met the performance requirements on the core products, it

[6] *CCPA Purchasing Partners Vaccine Contracting & Compliance Form*, *available at* https://www.ccpapp.org/assets/1/7/7._2016_Vaccine_Contracting_and_Compliance_Form_Fillable1.pdf.

[7] *CCPA Purchasing Partners Vaccine Contracting Guide*, *available at* https://www.ccpapp.org/assets/1/7/CCPAPP_Vaccine_Contracting_Guide_2016.pdf.

[8] *CASA Physicians Alliance Participation Agreement*, *available at* http://www.casaalliance.net/download/AAADM%20-B%20PARTICIPATION%20AGREEMENT%20CURRENT%20032917.pdf?inline.

provided penalty-free prices on the full-line of Merck vaccines, including Gardasil, MMRII, ProQuad, Varivax, and RotaTeq.[9]

5. Main Street Vaccines

130. Merck's agreement with the Main Street Vaccines PBG "requires the preferential use of: RECOMBIVAX, VAQTA, RotaTeq, Gardasil/Gardasil 9, [and] ZOSTAVAX."[10] Main Street Vaccines also has agreements with its individual members that require exclusivity to Merck's vaccines, and do not allow the customer to purchase any competing vaccines from GSK, such as Rotarix. According to the Main Street Vaccines' web page describing the agreements, "Members can use any combination of Merck vaccine *but may not use competing vaccines from other manufacturers*."[11]

6. Medical Practice Purchasing Group

131. Medical Practice Purchasing Group ("MPPG") offers special pricing and additional rebates to physician members. Under the MPPG contract, members agree "to use the full portfolio of vaccine-related pharmaceutical products covered under the MPPG contracts in the volume and ratios contemplated by the recommended immunization schedules."[12] MPPG pays rebates, which it calls "loyalty payments," to members "since our group pricing is based on brand loyalty. Members purchasing our contracted partners' products and not their competitors' can earn

---

[9] *Discount vaccines available to CASA Physician GPO members, available at* http://www.casaalliance.net/merck.

[10] *The Main Street Vaccines/Merck Agreement, available at* http://www.mainstreetvacs.com/merck-2/.

[11] *Id.* (emphasis added).

[12] *MPPG Member Agreement, available at* http://www.mppg.net/wp-content/uploads/2016/04/April-2016-participation_agreement_.pdf.

eligibility for these awards."[13] MPPG's FAQs also remind members that "[i]f you are interested in receiving the vaccine discounts, keep in mind our group pricing is based on our members purchasing Merck and/or Sanofi Pasteur vaccines and not their competitors."[14] This indicates that the contract between MPPG and Merck disincentivized the PBG from offering any vaccines to its members that compete with Merck's vaccines, such as Rotarix, or from making GSK vaccines available to its members. The FAQs also note that "Our compliance rates are exceptionally high and we appreciate our members' dedication to the group's benefit."[15]

7. National Discount Vaccine Alliance

132. National Discount Vaccine Alliance's ("NDVA") 2009 Membership Agreement for Merck vaccines required that NDVA and its members maintain a minimum level of 90% market share on RotaTeq and other Merck pediatric vaccines, or "be considered non-compliant and subject to immediate removal from the contract. This will be monitored no less than quarterly."[16] If a medical practice is non-compliant, it risks having penalties imposed as follows: 34% on purchases of Recombivax, 29% on purchases of Vaqta, 6% on purchases of RotaTeq, 3% on purchases of ProQuad, MMR, and Varivax, and 2% on purchases of Pneumovax 23, Zostavax and Gardasil.[17]

8. Unified Physicians Society

133. Unified Physicians Society ("UPS") is a for-profit PBG that has thousands of

---

[13] *FAQs, available at* http://www.mppg.net/membership/faqs/.

[14] *Id.*

[15] *Id.*

[16] *Membership Agreement, available at* http://nebula.wsimg.com/79e43736b37bf4e496ee7e8d092d1404?AccessKeyId=178AB8FC86C5F686B8A4&disposition=0&alloworigin=1.

[17] *Id.*

pediatrician members. UPS has negotiated market share agreements with Merck and Sanofi. According to UPS' FAQs, "[i]n order to receive the highest discounts, our members have chosen to utilize these product lines exclusively. The only vaccine our members do not purchase on contract is Pneumococcal Conjugate Vaccine for Pediatric Use, which is not available through Sanofi Pasteur or Merck."[18]

9. PedsPal

134. PedsPal, a GPO, has an agreement with Merck that is similar to CASA Physicians Alliance's agreement with Merck.[19]

10. River Valley Pediatricians, Inc.

135. River Valley Pediatricians, Inc. ("RVPI") is a group purchasing organization that serves 44 pediatric practices in greater Cincinnati, northern Kentucky, and southeast Indiana. It allows members to avoid penalties on their pricing on RotaTeq and other Merck vaccines in exchange for loyalty. RVPI's membership application "requires total purchasing support of those contracts that include 'loyalty/compliance' discount clauses that have been approved by the RVPI Board. These require achievement by all members collectively of market share purchases equal to or greater than 90% of total product purchases."[20] The agreement also states that "*[f]ailure to comply with these purchasing agreements will result in termination from the agreements*."[21]

C. Merck Works with PBGs to Enforce the Merck Bundle

136. Since 2008 and continuing to the present, Merck has worked together with PBGs to enforce the exclusionary terms of the Merck Bundle and to make sure that customers do not buy

[18] *FAQs, available at* http://www.unifiedphysicianssociety.com/index.php/faqs.

[19] *PedsPal Group Purchasing Program, available at* http://www.pedspal.org/SiteCollectionDocuments/Join/PEDSPAL-JoinNow.pdf.

[20] *RVPI Membership Application* (as of June 16, 2016).

[21] *Id.*

GSK's Rotarix. Merck enforces the contracts through the threat of higher prices for RotaTeq and other vaccines in the bundle as well as through the threat of withholding administrative fees and rebates from PBGs whose members purchase Rotarix from GSK. As a result, Merck incentivizes the PBG's to be coopted into helping Merck ensure that the PBG members do not buy Rotarix.

137. For example, CCPA Purchasing Partners' Vaccine Contracting Guide explains that "[b]ecause failure to meet contract compliance by practices may result in price increases and loss of administrative fees for ALL CCPAPP practices, we do not tolerate non-compliance within our contract terms. CCPAPP will notify your practice of any purchase activity that is not in compliance with our Merck agreement. If the non-compliance continues, we will promptly send written notice via certified mail to your practice informing you of your termination from our contract."[22]

138. Similarly, CASA Physicians Alliance's website explains that it "reviews individual member purchases on a continuous basis to insure individual clinic performance meets the participation requirements."[23] CNHN Vaccine Group explains that "[t]he closer our group comes to 100% contract purchase compliance, the better the pricing for all. CNHN will remove practices from CNHN contracts for failure to comply with contract terms."[24] A "Frequently Asked Questions" page on the Main Street Vaccines website explains that "[w]e get rock bottom prices on Sanofi Pasteur and Merck Vaccines by agreeing to their exclusive use. Main Street Vaccines and its member practices may not use competing vaccines except for explicit reasons of medical

[22] *CCPA Purchasing Partners Vaccine Contracting Guide*, *available at* https://www.ccpapp.org/assets/1/7/CCPAPP_Vaccine_Contracting_Guide_2016.pdf.

[23] *Discount vaccines available to CASA Physician GPO members*, *available at* http://www.casaalliance.net/merck.

[24] *Vaccine Group Purchase Programs*, *available at* https://childrensnational.org/healthcare-providers/physician-networks/childrens-national-health-network-cnhn/benefits-of-cnhn-membership/vaccine-group-purchase-programs.

necessity or product unavailability."[25]

139. PBGs also help Merck monitor their members' compliance with the Merck Bundle. For example, a question on the Main Street Vaccines "Frequently Asked Questions" page asks "Can you really tell if I am buying vaccines outside the contract?" The answer is "Yes, we can. When that happens you may receive a warning or a notice terminating your membership with the loss of all accrued benefits. Periodically, competing manufacturers 'advise' members of ways to skirt our agreements and use their products. This is almost always detected and results in removal from our contract(s)."[26] Similarly, Unified Physicians Society's "Frequently Asked Questions" page explains that "[o]ur contract member purchases are monitored by the manufacturers and our discounts/terms are based on members adhering to these guidelines."[27]

D. The Merck Bundle Has Substantially Foreclosed Competition in the Rotavirus Vaccine Market

140. By requiring their customers to purchase all or nearly all of their rotavirus vaccines from Merck, Merck's RotaTeq Bundled Loyalty Condition substantially foreclosed competition in the Rotavirus Vaccine Market. On information and belief, Merck's contracts containing the RotaTeq Bundled Loyalty Condition have foreclosed competition in greater than 40% of the relevant market.

141. GSK is the only competitor to Merck in the Rotavirus Vaccine Market, having received a license for Rotarix in April 2008 and entered the market shortly thereafter.

142. Because failure to comply with the RotaTeq Bundled Loyalty Condition can lead

---

[25] Kevin W. Caves & Hal J. Singer, *Bundles in the Pharmaceutical Industry: A Case Study of Pediatric Vaccines* at 25 n.56 (2011) (quoting *Frequently Asked Questions*, http://www.mainstreetvacs.com/faq.html).

[26] *Id.*

[27] *FAQs*, *available at* http://unifiedphysicianssociety.com/index.php/faqs.

to substantial penalties on a portfolio of other vaccines that physicians purchase from Merck (including those that they cannot get from anyone else), the contracts effectively raised the cost of purchasing Rotarix by a substantial degree. Even if GSK decided to counter the RotaTeq Bundled Loyalty Condition by offering Rotarix at a lower price than RotaTeq, physicians and hospital purchasers would have to weigh that difference against the penalty they would be forced to pay on *all* of their other vaccine purchases from Merck.

143. For example, assuming a physician practice purchased the ACIP recommended portfolio of pediatric vaccines for each of its patients, Merck's RotaTeq Bundled Loyalty Condition imposed penalties of $25.91 per rotavirus dose, which represents approximately 40% of Merck's nominal loyal RotaTeq price ($64.71). This means that GSK would have to price its competing rotavirus vaccine more than forty percent below Merck's Loyal price for RotaTeq in order to counterbalance the penalties the customer would have to pay on Merck's portfolio of vaccines. And GSK had no incentive to cut price in this way because the Merck Bundle was designed to, and did, ensure that even if Merck continued to price at monopoly levels, GSK could not gain sufficient sales from price cuts to foreclosed (Loyal) buyers to make such price cuts profitable.

144. GSK's ability to counter the RotaTeq Bundled Loyalty Condition with aggressive competition was made even more difficult because Merck offered multiple vaccines that GSK did not, including HPV, MMR, and Varicella vaccines. Given that these vaccines are required under the ACIP recommendations, physician buyers needed to purchase these products from Merck. GSK had no alternative to several of Merck's monopoly vaccines. Moreover, because ACIP recommends that patients complete their vaccination schedule using the same brand of vaccine for each dose, at any given point in time a substantial portion of the demand for Merck's vaccines by

physician practices and hospitals is incontestable, meaning that the customer cannot, consistent with good medical practice, switch *all* of its purchases to another supplier no matter what price is offered. Thus, the customer would still be forced to pay penalty prices on the remaining Merck vaccines that it could not switch to GSK.

145. As a result, the Merck Bundle reduced GSK's ability to compete for buyers foreclosed by the RotaTeq Bundled Loyalty Condition. This in turn reduced GSK's incentive to compete for market share in the Rotavirus Vaccine Market by reducing the price of Rotarix. The Merck Bundle prevented the erosion of Merck's market share and monopoly power, allowing Merck to foreclose a substantial share of the Rotavirus Vaccine Market and maintain high prices. Had Merck not used the Merck Bundle to foreclose competition in the Rotavirus Vaccine Market, GSK would have achieved greater sales at lower prices than it actually did and would have forced Merck to respond with lower prices to avoid losing substantial market share.

146. In addition, the Merck Bundle has prevented physician practices and hospital purchasers from making a free choice between RotaTeq and Rotarix based on price, quality, service, and clinical preference.

147. On information and belief, Merck has executed contracts containing the RotaTeq Bundled Loyalty Condition requiring *de facto* exclusivity or near exclusivity on RotaTeq, with PBGs and other GPOs and hospital networks covering the vast majority of private physician and hospital purchasers of rotavirus vaccines in the United States. Under the terms of these contracts, physicians and hospital purchasers must purchase all or nearly all of their rotavirus vaccines from Merck to avoid substantial pricing penalties on all of Merck's vaccines. On information and belief, these contracts collectively foreclosed more than 40% of the Rotavirus Vaccine Market, which is a substantial part of the available opportunities for the distribution of rotavirus vaccines in the

United States.

IX. ANTICOMPETITIVE HARM AND ANTITRUST IMPACT

148. The purpose and effect of the RotaTeq Bundled Loyalty Condition was to insulate Merck's RotaTeq from competition from GSK's Rotarix. By artificially dividing the Rotavirus market, the Merck Bundle prevented the price declines and market share erosion that would normally occur upon competitive entry into a market dominated by a monopolist. As a result, physicians and hospitals (Class members) paid substantially more for both RotaTeq and Rotarix than they otherwise would have.

149. As a result of the Merck Bundle, plaintiffs and members of the proposed class have repeatedly paid artificially inflated prices for rotavirus vaccines from the time Rotarix entered the market through the present.

A. Economic Theory Demonstrates How The Merck Bundle Leads to Higher Prices

150. A number of economists have explained how bundled loyalty contracts can increase profits and anticompetitively raise prices, resulting in harm to purchasers. Bundled loyalty contracts effectively function as market allocation agreements because they can result in the same outcome as would occur from horizontal agreements to divide customers, for example through a geographic market allocation agreement.[28]

151. In a competitive marketplace without any bundled loyalty contracts, the entrance of a second product such as Rotarix to compete with a former monopolist would cause prices to drop. This is because, absent collusion, competing firms acting in their own rational self-interest

---

[28] *See* Einer Elhauge, *How Loyalty Discounts Can Perversely Discourage Discounting*, 5 J. COMP. L. & ECON. 189 (2009); Einer Elhauge, *Tying, Bundled Discounts, and the Death of the Single Monopoly Profit Theory*, 123 HARV. L. REV. 397, 459-61 (2009); Einer Elhauge & Abraham L. Wickelgren, *Robust Exclusion and Market Division Through Loyalty Discounts*, 43 INT'L J. INDUS. ORG. 111 (2015).

will reduce their prices if by doing so they can gain or retain sufficient market share to offset the reduced profits on their existing sales due to the lower price. However, by imposing the RotaTeq Bundled Loyalty Condition in its contracts, Merck prevented this normal price competition from occurring by effectively bifurcating the Rotavirus Vaccine Market into two groups: (1) restrained (foreclosed) buyers who are subject to the RotaTeq Bundled Loyalty Condition who purchased many other Merck pediatric vaccines, and thus would face high penalties on those vaccines if they bought Rotarix (Merck Loyal Buyers), and (2) unrestrained buyers who were not subject to the bundled loyalty condition or did not buy other Merck vaccines, and thus faced little to no penalty for switching to Rotarix. As described above, the first group of restrained buyers was foreclosed from purchasing Rotarix due to Merck's bundled loyalty contracts, while the second group of unrestrained buyers was not foreclosed.

152. Because the RotaTeq Bundled Loyalty Condition effectively divided the market in this way, it changed GSK's profit-maximizing strategy from that which it would have employed under normal competitive circumstances. Because of the Merck Bundle, in order to convince a foreclosed (Merck Loyal) customer to purchase Rotarix, GSK would have to compensate the customer for the increased penalties that customer would be forced to pay on the other vaccines in the Merck Bundle. That limited the ability of GSK to compete for foreclosed customers and thus allowed Merck to retain a dominant share even as it continued to price at monopoly levels. Because GSK could not gain sufficient share from price cuts to such foreclosed (Loyal) buyers to make such price cuts profitable, the Merck Bundle decreased GSK's incentive to engage in price competition for such foreclosed buyers.

153. For unforeclosed buyers, the RotaTeq price was even higher than the monopoly price charged to Loyal Buyers, because Merck penalized customers with higher prices for not

committing to the Merck Bundle.

154. Given the size of the disloyalty penalties, and the fact that a significant portion of the demand for Merck's bundled vaccines is not subject to competition at least in the short run, the Merck Bundle was designed to, and did, foreclose a large enough share of the Rotavirus Vaccine Market to ensure that the profit-maximizing choice for GSK was to refrain from competing vigorously on price for both foreclosed and unforeclosed customers. As a result, purchasers of RotaTeq were robbed of the benefits of competition due to the Merck Bundle and forced to pay higher prices.

155. Because the Merck Bundle reduced GSK's ability to compete for foreclosed buyers, and thus reduced GSK's incentive to compete on price, it also led to increased Rotarix prices as well. That is, since the Merck Bundle effectively divided the market in a way that lessened the ability and incentive of GSK to compete with Merck, prices of both RotaTeq and Rotarix were higher than they would have been absent Merck's imposition of the Merck Bundle. Due to the conduct challenged herein, rotavirus vaccine prices were increased market-wide for foreclosed and un-foreclosed customers.

B. Instead of Decreasing RotaTeq Prices After Rotarix Entered the Rotavirus Vaccine Market, Merck Increased Prices or Kept Them Constant

156. Consistent with the economic theory discussed above, instead of significantly decreasing the price of RotaTeq when GSK entered the market, as would normally be expected to result from competitive entry into a monopoly market, Merck has maintained the price of RotaTeq at supracompetitive levels, actually *increasing* its list price over time.

157. The following table illustrates the private sector list price per dose for RotaTeq in each year since it was introduced in 2006. Merck's anticompetitive conduct insulated it from competition, preventing prices from falling in response to the introduction of Rotarix in 2008 and

instead allowing Merck to *increase* list prices:

Date	Price per dose
Apr. 2006	$63.25
May 2007	$66.94
Sept. 2008	$69.59
Dec. 2009	$69.59
Dec. 2010	$69.59
Dec. 2011	$69.59
Nov. 2012	$72.34
Nov. 2013	$75.20
Dec. 2014	$75.20
Nov. 2015	$78.18
Dec. 2016	$81.28
Dec. 2017	$82.89

X. CONTINUING VIOLATION

158. From 2008 and continuing to the present day, Merck has entered into new contracts containing the exclusionary RotaTeq Bundled Loyalty Condition.

159. From 2008 and continuing to the present day, Merck has enforced and threatened to enforce the terms of the RotaTeq Bundled Loyalty Condition.

160. From 2008 and continuing to the present day, Merck's anticompetitive scheme has allowed it to repeatedly overcharge Class members throughout the United States for RotaTeq, with each sale causing additional anticompetitive harm.

XI. CLASS ACTION ALLEGATIONS

161. Plaintiffs bring this action on behalf of themselves and all others similarly situated pursuant to Rule 23 of the Federal Rules of Civil Procedure as representative of a class defined as follows:

> All persons or entities in the United States and its territories that purchased RotaTeq directly from Merck or any of its divisions, subsidiaries, predecessors, or affiliates, during the period from April 25, 2014 through such time as the effects of Merck's illegal conduct have ceased, and excluding all governmental entities, Merck, and Merck's divisions, subsidiaries, predecessors, and any purchases by entities buying RotaTeq pursuant to a publicly-negotiated price (*i.e.*, governmental purchasers).

162. On information and belief, hundreds or thousands of entities in the United States have purchased rotavirus vaccines directly from Merck. Thus, the class is so numerous and geographically dispersed that joinder is impracticable.

163. Plaintiffs' claims are typical of those of the class.

164. Plaintiffs and all members of the class were injured in the form of overcharges by the same conduct of the defendant.

165. Plaintiffs will fairly and adequately protect and represent the interests of the class. The interests of the plaintiffs are not antagonistic to the class.

166. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of complex class action antitrust litigation.

167. Questions of law and fact common to the members of the class predominate over questions, if any, that may affect only individual members because Merck has acted and refused to act on grounds generally applicable to the entire class. Such generally applicable conduct is inherent in Merck's exclusionary and anticompetitive conduct in monopolizing and attempting to monopolize the Rotavirus Vaccine Market, as more fully alleged herein.

168. Questions of law and fact common to the class include:

a. whether Merck intentionally and unlawfully impaired or impeded competition in the Rotavirus Vaccine Market;

b. whether Merck maintained or enhanced monopoly power in the Rotavirus Vaccine Market;

c. whether Merck engaged in anticompetitive conduct in order to unlawfully disadvantage its competitors and maintain monopoly power in the Rotavirus Vaccine Market;

d. whether Merck had and has monopoly power in the MMR, Varicella, HPV, and Rotavirus Vaccine Markets;

e. whether Merck had procompetitive reasons for its conduct;

f. the effects of Merck's anticompetitive conduct on rotavirus vaccine prices;

g. whether plaintiffs and other members of the class have been overcharged and thus damaged by paying artificially inflated prices for rotavirus vaccines as a result of Merck's unlawful behavior; and

h. the proper measure of damages.

169. Class action treatment is a superior method for the fair and efficient adjudication of the controversy in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of effort and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that might not be practicable for them to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

170. Plaintiffs know of no difficulty to be encountered in the maintenance of this action as a class action.

FIRST CAUSE OF ACTION
Monopolization of the Rotavirus Vaccine Market (15 U.S.C. § 2)

171. Plaintiffs incorporate by reference the above allegations.

172. At all relevant times, Merck had monopoly power in the MMR, Varicella, HPV, and Rotavirus Vaccine Markets. During much of the relevant period, Merck had market power in the Hepatitis A and Hepatitis B Pediatric Vaccine Markets.

173. Merck has willfully maintained its monopoly power in the Rotavirus Vaccine Market through exclusionary and anticompetitive means. Merck leveraged its monopoly power in the MMR, Varicella, HPV, and Rotavirus Vaccine Markets by imposing contractual terms on purchasers of its vaccines that penalized customers for buying rotavirus vaccines from rivals such as GSK. Since at least 2008, Merck's RotaTeq Bundled Loyalty Condition unfairly impaired the incentive of rivals such as GSK to compete for market share, and has thus preserved Merck's monopoly power in the market for rotavirus vaccines.

174. By engaging in this exclusionary conduct as alleged herein, Merck has gained an artificial and unlawful advantage in the Rotavirus Vaccine Market from its monopoly power in a variety of vaccine markets, as opposed to by offering products with lower prices or higher quality. As a result, Merck has unfairly impeded competition in the Rotavirus Vaccine Market. The purpose and effect of Merck's conduct has been to suppress competition rather than to promote it.

175. By suppressing competition and maintaining its monopoly power, Merck has been able to artificially inflate the price of RotaTeq above levels that would have prevailed in a world without Merck's anticompetitive conduct alleged herein. In addition, because Merck's conduct removed price cutting as an effective competitive response for GSK, Rotarix's price was higher

than it otherwise would have been. Accordingly, the challenged conduct caused plaintiffs and members of the proposed class to pay artificially inflated prices for rotavirus vaccines sold into the private market.

176. There are no procompetitive justifications for Merck's conduct.

177. Plaintiffs have been injured in their business and property by reason of Merck's unlawful monopolization. Plaintiffs' injuries consist of paying higher prices to purchase rotavirus vaccines than they would have paid absent Merck's unlawful conduct as alleged herein. Plaintiffs' injuries are of the type the antitrust laws were designed to prevent and flow from that which makes Merck's conduct unlawful.

SECOND CAUSE OF ACTION
Anticompetitive Agreements in Unreasonable Restraint of Trade (15 U.S.C. § 1)

178. Plaintiffs incorporate by reference the above allegations.

179. At all relevant times, Merck had monopoly power in the MMR, Varicella, HPV, and Rotavirus Vaccine Markets. During much of the relevant period, Merck had market power in the Hepatitis A and Hepatitis B Pediatric Vaccine Markets.

180. Merck entered into a series of unlawful exclusionary agreements with PBGs, hospital groups, and other GPOs whose purpose and effect was to unreasonably restrain competition in the Rotavirus Vaccine Market by penalizing customers with high prices on a portfolio of vaccines if the customer did not agree to refrain from purchasing rotavirus vaccines from Merck's rivals.

181. Merck entered into agreements with PBGs to enforce the RotaTeq Bundled Loyalty Condition. These agreements included written exclusionary agreements in unreasonable restraint of trade.

182. There was no legitimate business justification for these agreements and these

agreements: (a) substantially foreclosed and excluded competition from rotavirus vaccine manufacturers; and (b) resulted in Merck's willful maintenance and unlawful exercise of monopoly power in the Rotavirus Vaccine Market.

183. At all relevant times, Merck's exclusionary agreements assisted Merck in: (a) effectively excluding less expensive competitive products from the Rotavirus Vaccine Market; (b) maintaining Merck's dominant market share and monopoly power in the Rotavirus Vaccine Market; (c) maintaining prices at artificially high levels for RotaTeq; and (d) otherwise reaping the benefits of its illegal monopoly power.

184. None of the claims of plaintiffs or class members in this matter flows from provisions of its particular contract with a PBG standing alone, or from provisions in any PBG or GPO contract with Merck standing alone. Rather, plaintiffs allege here that all of the contracts at issue that contain or pertain to enforcing the RotaTeq Bundled Loyalty Condition *taken together* form part of the anticompetitive bundling scheme at issue.

185. There is no procompetitive justification for Merck's conduct.

186. Plaintiffs have been injured in its businesses and property by reason of the alleged collusion and conspiracy, which facilitated, enabled, assisted, and furthered Merck's substantial foreclosure and exclusion of competition and monopolization of the Rotavirus Vaccine Market. Plaintiffs' injuries consist of paying higher prices to purchase RotaTeq and Rotarix than they would have paid absent Merck's unlawful conduct. Plaintiffs' injuries are of the type the antitrust laws were designed to prevent and flow from that which makes Merck's conduct unlawful.

XII. PETITION FOR RELIEF

WHEREFORE, plaintiffs petition that:

187. The Court determine that this action may be maintained as a class action pursuant to Federal Rule of Civil Procedure 23, that plaintiffs be appointed as class representatives, and that plaintiffs' counsel be appointed as counsel for the class;

188. The conduct alleged herein be declared, adjudged, and/or decreed to be unlawful under Section 1 and Section 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2;

189. Plaintiffs and the class recover their overcharge damages on their purchases of RotaTeq and Rotarix, trebled, and the costs of the suit, including reasonable attorneys' fees as provided by law; and

190. Plaintiffs and the class be granted such other and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

XIII. JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury of all of the claims asserted in this complaint so triable.

Respectfully submitted,

Dated: June 15, 2018

BERGER & MONTAGUE, P.C.

Eric L. Cramer (PA ID 69289)
Zachary D. Caplan
Karissa Sauder
1622 Locust Street
Philadelphia, PA 19103

COHEN MILSTEIN SELLERS
& TOLL PLLC
Daniel A. Small
1100 New York Ave. NW Suite 500
Washington, DC 20005
Tel: (202) 408-4600
Fax: (202) 408-4699
dsmall@cohenmilstein.com

Daniel H. Silverman
190 South LaSalle Street, Suite 1705
Chicago, IL 60603
Tel: (202) 408-4600

Tel: (215) 875-3000
Fax: (215) 875-4604
ecramer@bm.net
zcaplan@bm.net
ksauder@bm.net

Daniel J. Walker
2001 Pennsylvania Avenue, N.W., Suite 300
Washington, DC 20006
Tel: (202) 559-9745
dwalker@bm.net

Interim Co-Lead and Liaison Counsel
for the Proposed Class

dsilverman@cohenmilstein.com

Gary L. Azorsky
1717 Arch Street, Suite 3610
Philadelphia, PA 19103
Tel: (267) 479-5700
gazorsky@cohenmilstein.com

Interim Co-Lead Counsel
for the Proposed Class

HAUSFELD LLP
Brent W. Landau
Gary I. Smith
325 Chestnut Street, Suite 900
Philadelphia, PA 19106
Tel: (215) 985-3270
blandau@hausfeld.com
gsmith@hausfeld.com

GAVIN LAW LLC
Michael Gavin
855 Hillsdale Road
West Chester, PA 19382
Tel: (610) 918-7271
mgavin@gavinlaw.net

NUSSBAUM LAW GROUP, P.C.
Linda P. Nussbaum
Hugh D. Sandler
1211 Avenue of the Americas, 40th Floor
New York, NY 10036
Tel: (917) 438-9102
lnussbaum@nussbaumpc.com
hsandler@nussbaumpc.com

Additional Counsel for the Proposed Class

CERTIFICATE OF SERVICE

I hereby certify that on June 15, 2018, the foregoing complaint was filed with the Clerk of Court who will file the complaint using the CM/ECF system, which will send notification and a copy of such filing to all counsel of record.

s/ Eric L. Cramer
Eric L. Cramer